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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/737,176	12/13/2000	Josef V. Koblish	15916-279	8413

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EXAMINER
PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 01/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

C.C.

Office Action Summary	Application No.	Applicant(s)	
	09/737,176	KOBLISH ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-11,15-25,33 and 36-48* is/are rejected.

7)☒ Claim(s) *12-14,26-28 and 38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14+17
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicant's amendments and comments, received December 13, 2002, have been fully considered. The following is a complete response to the December 13, 2002 communication.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1 and 15 recite an inflatable element that allows "substantially no liquid perfusion therethrough". Claims 5 and 17 then recite that the inflatable member contains a plurality of micropores which presumably would allow for the perfusion of a liquid. It is unclear what specifically is meant by "substantially no liquid perfusion" and how the microporous member meets this criteria. For the purpose of applying prior art, microporous members will be deemed to meet the limitation of allowing "substantially no liquid perfusion".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33, 36, 37, 39-43 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Gough et al ('484).

With regard to claim 33, Gough et al disclose a device which includes a hollow needle (14) and a therapeutic assembly (16) located within and movable relative to the needle. The assembly includes a relatively short shaft and an inflatable, energy transmitting element (23) associated with a distal portion of the shaft. Column 6, lines 34-57 disclose the particulars of the inflatable member, including disclosure that the inflatable member may be implanted with conductive ions and have micropores for the delivery of an electrolytic fluid and energy.

Concerning claim 39-43 and 45, the Gough et al device comprises a surgical probe (16) having a relatively short shaft with an inflatable, energy transmitting portion (23) associated with the distal end, and a cooling fluid source connected to the inflatable energy transmitting element and adapted to maintain pressure at a predetermined level (controlled by the fluid flow rate). While Gough et al do no expressly state that the fluid is a "cooling fluid", the examiner maintains that it inherently serves that function since it is a flowing fluid provided at a lower temperature (i.e. ambient temperature) than the heat-generating electrode. The fluid is inherently continuously infused and ventilated since there are micropores for delivery of the fluid from the balloon.

Claims 39-43 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Qian ('028).

Qian provides a device with a relatively short shaft (10) with an inflatable, energy transmitting element (18) located at the distal portion of the shaft. A fluid is provided to the inflatable member under sufficient pressure to inflate the balloon. Also, the fluid would have inherent cooling properties since it is lower in temperature than the heated energy delivery element, and further since the fluid is continuously infused and vents through micropores in the balloon (see Abstract and col. 2, lines 13-19). The shaft is deemed to be relatively short as it is used in the esophagus (col. 2, lines 8-12) which does not require a lengthy or flexible tube.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5-8, 11, 15-20, 24, 25 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qian ('028) in view of the teaching of Deslauriers et al ('678)

As addressed previously with respect to the 35 USC 102(b) rejection, Qian discloses a device which comprises a relatively short shaft (10) with an inflatable, energy transmitting lesion formation element (18) associated with the distal portion of the shaft. Qian fails to specifically teach that the shaft is relatively stiff and/or malleable. However, Qian does teach that the device is an esophageal device.

Deslauriers et al disclose an analogous device which comprises a relatively short, relatively stiff shaft having a balloon member at the distal end for esophageal

applications. In particular, Deslauriers et al teach that it is desirable to provide the relatively short shaft with a malleable configuration support (col. 9, lines 1-7) to aid in the insertion of the device into the esophagus.

Concerning claims 6-8 and 18-20, the entire surface of the Qian device is deemed to be an energy transmission region and includes a distally facing region (i.e. at the distal end of the balloon) and a proximally facing region and surrounds a non-conductive region (shaft 10).

To have provided the Qian device with a malleable shaft to facilitate its insertion into the esophageal space would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Deslauriers et al.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Qian ('028) and Deslauriers et al ('678) as applied to claim 3 above, and further in view of the teaching of Lundquist (923).

The combination of Qian with the Deslauriers et al teaching has been addressed. There is no specific teaching in Deslauriers et al of providing varying degrees of malleability along the length of the device.

Lundquist provides a general teaching that it is known to provide varying degrees of malleability along the length of a shapeable medical device. More particularly, Lundquist teaches that it is desirable to provide the distal portion of a device with more flexibility than the proximal portion (col. 24, lines 1-30).

To have provided the Qian device, as modified by the teaching of Deslauriers et al, with a more flexible distal portion to facilitate locating the distal (i.e. active portion) of the device in tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Lundquist.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qian ('028) and Deslauriers et al ('678) as applied to claim 3 above, and further in view of the teaching of Swanson et al ('513).

The combination of Qian and Deslauriers has been addressed. Qian fails to disclose discrete energy transmitting and non-conductive regions on the balloon. Rather, the entire balloon serves as an energy transmitting member.

Swanson et al disclose an analogous energy transmitting balloon device, and specifically teach that the balloon may be provided with discrete energy transmitting and non-conductive regions on the balloon. The regions are dispersed along the balloon and may include annular portions facing distally and proximally (Figures 11 and 12). The conductive and non-conductive regions are visually distinctive and would be different colors due to the difference in materials.

To have provided the Qian device, as modified by the teaching of Deslauriers et al, with a plurality of conductive and non-conductive regions along the length of the balloon to provide a distinct energy emitting characteristic would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Swanson et al.

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qian ('028) and Deslauriers et al ('678) as applied to claim 3 above, and further in view of the teachings of Edwards ('241) and Abele et al ('311).

Qian discloses a means to provide a pressurized fluid to the balloon member such that fluid is perfused through micropores in the balloon. However, Qian fails to teach the particular pump and pressure control system, including a pressure sensor, for controlling the flow of fluid.

Edwards provides a substantially identical device to that of Qian. It includes an energy emitting balloon member, and means to provide pressurized fluid to the balloon such that the fluid is perfused through micropores in the balloon. Edwards specifically states that the fluid source may include a pump/pressure flow control device as is known in the art (col. 9, lines 1-15) and that the flow rate and pressure may be controlled (col. 10, lines 25-30). While the examiner holds that it is inherent that there is a means to monitor fluid pressure in order to control the pressure, there is no explicit of a pressure sensor used with the Edwards device. Abele et al disclose a balloon device with a fluid pump source, and specifically teach of the known use of a pressure sensor (9) located on the device for controlling the operation of a pump to provide a desired fluid flow.

To have provided the Qian device with a fluid pressure and flow control system, including a pressure sensor, to provide a desired fluid flow through the balloon would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Edwards and Abele et al.

Claims 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Gough et al ('484) or Qian ('028) in view of the teachings of Edwards ('241) and Abele et al ('311).

As addressed in the 35 USC 102 rejections, both Gough et al and Qian disclose systems which include porous balloons which receive and perfuse a fluid (i.e. electrolytic solution). While Gough et al inidicate that fluid flow/pressure may be controlled (col. 10, lines 1-7), neither reference shows the specific components to achieve the monitoring and control of a fluid within the balloon device.

Edwards provides a substantially identical device to that of Qian. It includes an energy emitting balloon member, and means to provide pressurized fluid to the balloon such that the fluid is perfused through micropores in the balloon. Edwards specifically states that the fluid source may include a pump/pressure flow control device as is known in the art (col. 9, lines 1-15) and that the flow rate and pressure may be controlled (col. 10, lines 25-30). While the examiner holds that it is inherent that there is a means to monitor fluid pressure in order to control the pressure, there is no explicit of a pressure sensor used with the Edwards device. Abele et al disclose a balloon device with a fluid pump source, and specifically teach of the known use of a pressure sensor (9) located on the device for controlling the operation of a pump to provide a desired fluid flow.

To have provided either the Gough et al or the Qian device with a fluid pressure and flow control system, including a pressure sensor, to provide a desired fluid flow

through the balloon would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Edwards and Abele et al.

Allowable Subject Matter

Claims 12-14, 26-28 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Michael Peffley
Primary Examiner
Art Unit 3739

mp
January 16, 2003